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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,750	01/25/2001	Michael S. Parmacek	ARCD:333-1WI	4391

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/381,750

Applicant(s)

PARMACEK ET AL.

Examiner

Terry A. McKelvey

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-39 and 45-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-44 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/3/00; 7/24/00.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group II, claims 40-44 and 53 in the reply filed on 8/3/04 is acknowledged.

Claims 1-39 and 45-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/3/04.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when

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the reference is to a prior application of a CPA assigned the same application number.

In the instant case, the application contains references to priority in the oath/declaration to particular applications. This claim for priority must also be in the first sentence of the specification or in an application data sheet.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 40-44 and 53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to the genus including the claimed method using any SM22a promoter region. Thus, the claims are drawn to a genus of methods that is defined their use of a genus

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of nucleic acids, those that comprise an SM22a promoter region from the SM22a gene of any organism that has an SM22a gene, which also includes any allelic variants thereof.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factor present in the claims or the specification is that the specification sets forth the complete description of only one SM22a promoter, which is a particular sequence contained in the sequence of SEQ ID NO:1. There is no description of other SM22a promoter regions. There is no description of how the promoter region of SEQ ID NO:1 relates to other SM22a promoter regions in other organisms, for example. There is no description of the SM22a promoter regions for different allelic variants of SM22a for the described SM22a gene (murine SM22a gene) or for the SM22a gene in other organisms. Promoter regions for the same gene in different organisms are known in the art to be very divergent, much less conserved than the structural genes, which

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are often not very highly conserved themselves. Thus, the promoter region of the gene from one organism is not predictive of the structure of the promoter region from a different organism or even different allelic variant.

Accordingly, in the absence of sufficient recitation of distinguishing characteristics, the specification does not provide adequate written description of the claimed genus which encompasses the claimed method using any SM22a promoter region.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."

(See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is now is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of SM22a promoter regions to be used in the claimed method, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or identification. Adequate written description requires more than a mere statement that it is part

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of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the claimed method drawn to the use of the specific sequence containing the SM22a promoter in SEQ ID NO:1, but not the full breadth of the claims meets the written description provision of 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-44 and 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 40, etc the use of "an SM22a promoter region" renders the claims vague and indefinite because the metes and bounds of what constitutes such a region is unclear. Does this term encompass only the entire nucleic acid sequence which is responsible for the transcription control of an SM22a gene? Or, does this term also encompass a nucleic acid sequence that comprises any part of the SM22a promoter, including those that have no promoter function (and in which the isolated nucleic acid sequence also comprises some other promoter not specifically identified which allows the express to occur)? Or, does this term also encompass only a part of the SM22a promoter which has promoter activity? For the purposes of examination, the first interpretation, which is closest to what usually is intended in the art, is used.

Regarding claim 42, the use of "said cell cycle regulatory gene operatively linked to an SM22a promoter region comprises a viral or plasmid vector" renders the claims vague and indefinite because it is unclear how a cell cycle regulatory gene linked to a promoter region, neither of which is a vector, can comprise a vector. Amending claim 42 to recite "wherein said isolated

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nucleic acid segment further comprises a viral or plasmid vector." instead would be remedial.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 40-44 and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-7, 10-12, and 16 of U.S. Patent No. 6,114,311. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from

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the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40-44 and 53 are generic to all that is recited in claims 1-3, 5-7, 10-12, and 16 of U.S. Patent No. 6,114,311. That is, claims 1-3, 5-7, 10-12, and 16 of U.S. Patent No. 6,114,311 fall entirely within the scope of claims 40-44 and 53 or, in other words, claims 40-44 and 53 are anticipated by claims 1-3, 5-7, 10-12, and 16 of U.S. Patent No. 6,114,311. Specifically, the method of modulating smooth muscle proliferation (drawn to the use of a specific SM22a promoter sequence and using particular cell cycle regulatory genes which are inhibitory) of '311 is entirely encompassed by the method of inhibiting smooth muscle proliferation of instant claims 40-44 and 53.

Claims 40-44 and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-8, 11-14, 16-18, and 21 of U.S. Patent No. 6,284,743 B1. Although the conflicting claims are

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not identical, they are not patentably distinct from each other because of the following reasons.

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40-44 and 53 are generic to all that is recited in claims 1-4, 6-8, 11-14, 16-18, and 21 of U.S. Patent No. 6,284,743 B1. That is, claims 1-4, 6-8, 11-14, 16-18, and 21 of U.S. Patent No. 6,284,743 B1 fall entirely within the scope of claims 40-44 and 53 or, in other words, claims 40-44 and 53 are anticipated by claims 1-4, 6-8, 11-14, 16-18, and 21 of U.S. Patent No. 6,284,743 B1. Specifically, the method of modulating smooth muscle proliferation (drawn to the use of a specific SM22a promoter sequence and using particular cell cycle regulatory genes which are inhibitory) of '743 is entirely encompassed by

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the method of inhibiting smooth muscle proliferation of instant claims 40-44 and 53.

Claims 40-44 and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,291,211 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40-44 and 53 are obvious from what is recited in claims 1-32 of U.S. Patent No. 6,291,211 B1 because the limitations of claims 1-32 of '211 contain all of the limitations of instant claims 40-44 and 53 or are drawn to limitations that are totally

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encompassed by the limitations of claims 40-44 and 53 (the specific SM22a sequence of '211, for example). It would have been obvious to mix and match the limitations of the method of expressing a polypeptide of claims 1-32 of '211 to result in inventions of varying scope, including inventions that are totally encompassed by claims 40-44 and 53, because the different limitations of claims 2-32 are dependent on claim 1 or corresponding subject matter and thus it would have been obvious that these limitations could be present in different combinations, including those that are totally encompassed by claims 40-44 and 53. Those obvious claims would fall entirely within the scope of claims 40-44 and 53 or, in other words, claims 40-44 and 53 are anticipated by the obvious claims from claims 1-32 of U.S. Patent No. 6,291,211 B1. Specifically, the obvious claims based upon the method of expressing a polypeptide (drawn to the use of a specific SM22a promoter sequence and using particular cell cycle regulatory genes which are inhibitory) of '211 is entirely encompassed by the method of inhibiting smooth muscle proliferation of instant claims 40-44 and 53.

Claims 40-44 and 53 are rejected under the judicially created doctrine of obviousness-type double patenting as being

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unpatentable over claims 1-4, 7-10, and 18-24 of U.S. Patent No. 6,331,527 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

An obviousness-type double-patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 40-44 and 53 are generic to all that is recited in claims 1-4, 7-10, and 18-24 of U.S. Patent No. 6,331,527 B1. That is, claims 1-4, 7-10, and 18-24 of U.S. Patent No. 6,331,527 B1 fall entirely within the scope of claims 40-44 and 53 or, in other words, claims 40-44 and 53 are anticipated by claims 1-4, 7-10, and 18-24 of U.S. Patent No. 6,331,527 B1. Specifically, the method for providing a molecule of interest to a blood vessel in a mammal (drawn to the use of a specific SM22a promoter sequence and using particular cell cycle regulatory genes which are

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inhibitory) of '527 is entirely encompassed by the method of inhibiting smooth muscle proliferation of instant claims 40-44 and 53.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 703-872-9306. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance.

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Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

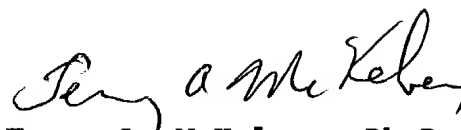
For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (571) 272-0775. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be

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responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel can be reached at (571) 272-0781.


Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

October 17, 2004